

REMARKS

Applicants gratefully acknowledge the telephonic interview that was held between the Examiner and Applicants' undersigned attorney on October 27, 2004. Applicants believe that the interview was quite helpful in focusing Applicants' efforts to advance the prosecution of this application. Applicants also appreciate the Examiner's efforts in advancing the prosecution of this application by providing specific, helpful suggestions throughout the Office Action.

A. Claim Objections

Claims 10-13, 15 and 20-22 stand objected to because of the following informalities:

(1) Claims 10-13 and 20-22 are drawn to methods of making crystalline forms of Compound (1) and product-by-process claims. While it is assumed that the product is formed at the conclusion of the last step, the instant claims fail to indicate such.

In response, these claims have been amended according to the first amendment suggested by the Examiner in the Office Action, thus rendering this objection moot.

(2) Claim 15 is objected to for the stated typographical error. In response, this claim has been amended as suggested by the Examiner in the Office Action, thus rendering this objection moot.

(3) Claim 23 is objected to as being in improper form because a multiple dependent claim can only depend from previous claims in the alternative. In response, this claim has been amended to avoid improper multiple dependency. Support for mixtures of different crystalline forms of Compound (1) as covered by amended claim 23 is found at page 18 of the specification and in original claim 23.

B. Rejections Under 35 USC 102 and 103

(1) Claims 12, 13, 22 and 24 stand rejected under 35 USC 102(b) as anticipated by, or under 35 USC 103(a) as obvious over WO 00/59929 A1.

(2) Claims 12, 13, 22, 24 and 25 stand rejected under 35 USC 102(e) as anticipated by, or under 35 USC 103(a) as obvious over US Patent 6,608,027 B1.

(3) Claims 12, 13, 22 and 24-26 stand rejected under 35 USC 103(a) as obvious over WO 00/59929 A1.

(4) Claims 12, 13, 22 and 24-26 stand rejected under 35 USC 103(a) as obvious over US Patent 6,608,027 B1.

With respect to both cited references, WO 00/59929 A1 and US Patent 6,608,027 B1, the Examiner argues that:

(1) while these references are silent regarding the morphology of compound #822 therein, it is the Examiner's position, absent evidence to the contrary, that the crystalline phase is an inherent physical trait of the compound, and that the method of Example 34 would result in a crystalline phase meeting the limitations of the instant claims. Therefore, the teachings of the references appear to anticipate the claimed invention.

(2) Even if the product is not identical to the referenced product, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced product is likely to inherently possess the same characteristics of the claimed product.

Applicants respectfully submit that the cited references fail to anticipate or render obvious the presently claimed invention under 35 USC 102 or 103, since the cited references fail to teach, disclose or suggest the preparation of compound #822 in a crystalline phase as instantly claimed.

It is the Examiner's stated position that, absent evidence to the contrary, the crystalline phase is an inherent physical trait of the compound [#822], and that the method of Example 34 would result in a crystalline phase meeting the limitations of the instant claims. At page 11 of the Office Action, the Examiner further mentions that Applicants may show evidence that the compounds prepared by the method in the prior art are not crystalline in morphology as instantly claimed to overcome the art rejections.

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In response thereto, Applicants have conducted experiments to confirm that the synthetic procedure of Example 34 in the cited references results in the formation of an amorphous, non-crystalline material. First, Applicants herewith present the Declaration of Vida Gorys, a trained chemist and Research Associate I at Boehringer Inhelheim (Canada) Ltd.. As stated in her Declaration, Ms. Gorys prepared compound #822 according to the same synthetic procedure of Example 34C in the cited references, with only two minor modifications of the process not affecting the final product obtained. Second, Applicants present herewith the Declaration of Dr. John Smoliga, a trained solid-state chemist and Principal Scientist in the Analytical Sciences Department at Boehringer Inhelheim Pharmaceuticals, Inc. As stated by Dr. Smoliga in his Declaration, the compound prepared by Vida Gorys was then tested and evaluated by X-ray powder diffraction, and found to be an amorphous, non-crystalline material.

In view of the above, Applicants submit that the evidence presented demonstrates that compound #822 prepared by the method disclosed in the cited references is not crystalline. Accordingly, the cited references cannot anticipate the present claims. Furthermore, there is no teaching, suggestion or enablement in the cited references of any method for preparing compound #822 in crystalline form. Accordingly, the cited references cannot render obvious the present claims. Withdrawal of these rejections is therefore respectfully requested.

C. Double Patenting Rejection

Claims 12, 13, 22 and 24-26 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 108, 115 and 143 of US Patent 6,608,027 B1. As a basis for this rejection, the Examiner presents essentially the same arguments as were presented in the rejections under 35 USC 102 and 103 mentioned above. In response, Applicants again point out that the evidence presented demonstrates that compound #822 prepared by the method disclosed in the cited reference is not crystalline. Furthermore, there is no teaching, suggestion or enablement in the cited reference of any method for preparing compound #822 in crystalline form. Accordingly, the cited reference cannot render obvious the present claims and, likewise, cannot form the basis for an obviousness-type double patenting rejection of the present claims. Withdrawal of this rejection is therefore respectfully requested.


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Applicants further appreciate the Examiner's indication of allowable subject matter at page 10 of the Office Action.

In view of the above amendments and remarks, and the attached Declarations, Applicants respectfully submit that this application is now in condition for allowance and earnestly request such action.

If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,


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